

K052899

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**510(k) Summary Information**  
**Premarket Notification, Section 510(k)****Genesee BioMedical, Inc.**  
**JUNE 28, 2005****Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92**1. Device Name:****Trade Name:** ATS SIMULUS FC Annuloplasty Band Model 700FC**Common****Name(s):** Annuloplasty Ring**Classification****Name(s):** Ring, Annuloplasty**2. Establishment Name & Registration Number:****Name:** Genesee BioMedical, Inc.**Number:** 1723241**3. Classification(s):****Device Class:** Class II**Classification Panel:** Cardiovascular Devices Panel**Product Code(s):** KRH**4 Equivalent Predicate Device:**

**K905175, PTI Annuloplasty Ring (Sterile), Now called the Genesee BioMedical, Inc. Sculptor® Annuloplasty Ring.**

Equivalence can be seen in the design, material composition, surgical technique and intended use.

**5. Device Description:**

The ATS SIMULUS FC Annuloplasty Bands are implantable, fully flexible, annular bands (Figure 1). The bands reduce and stabilize the atrioventricular annulus in patients undergoing mitral or tricuspid valve repair. The body of the band is made of braided Polyester. The band contains a circumferential flexible radiopaque marker. The entire circumference of the band is radiopaque.

The annuloplasty bands and accessories are designed as an integrated system to ease implantation. Malleable stems connects the double ended sizers to their handle.

The bands are available in the following sizes: 23 mm, 25 mm, 27 mm, 29 mm, 31 mm, 33 mm and 35 mm. The size refers to the inner diameter of the band. Green trigone markers are spaced at 120° from the midpoint of the posterior segment, which is also indicated by a green marker.

**6. Packaging:**

The ATS SIMULUS FC Annuloplasty Bands are supplied STERILE (sterilized by gamma radiation) and non-pyrogenic, packaged in inner and outer blister trays with peelable lids. Each band is mounted on a disposable holder. The bands will remain sterile until at least the expiration date provided the package is unopened and undamaged.

**7. Indications for Use:**

The ATS SIMULUS FC Annuloplasty Bands are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for the mitral or tricuspid annulus and restrict expansion of the annulus

**8. Testing Summary:**

Testing included LAL, Sterility Validation, Class IV Biocompatibility tests on the predicate device. Mechanical testing was carried out on complete modified bands and band components. All test results were satisfactory.

**9. Applicant Name & Address:**

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Denver, CO 80223  
Phone (303) 777-3000 extension 111  
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**10. Registration Number:**

1723241

**11. Company Contact:**

John Wright, Ph.D.  
Genesee BioMedical, Inc.

**12. Submission Correspondent:**

John T. M. Wright, Ph. D.  
Chief Executive Officer  
Genesee BioMedical, Inc.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Genesee BioMedical, Inc.  
c/o John T. M. Wright, Ph.D.  
Chief Executive Officer  
1308 S. Jason Street  
Denver, CO 80223-3408

Re: K052899  
ATS SIMULUS FC Annuloplasty Band Model 700FC  
Regulation Number: 21 CFR 870.3800  
Regulation Name: Annuloplasty Ring  
Regulatory Class: Class II (Two)  
Product Code: KRH  
Dated: October 12, 2005  
Received: October 14, 2005

Dear Dr. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number : K052899Device Name(s): ATS SIMULUS Annuloplasty Band**Indications For Use:**

The Genesee BioMedical ATS SIMULUS 700FC Annuloplasty Bands are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.

Prescription Use X OR Over-The-Counter Use \_\_\_\_\_PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional format 1-2-96)

Donna Holmes  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K052899